K010352

01/31/2001

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510(k) Summary for the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System

ADMINISTRATIVE INFORMATION

Manufacturer´s Name: Inion Ltd.
Sorinkatu 3
FIN-33100 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Coordinator
Sorinkatu 3
FIN-33100 Tampere
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DEVICE NAME

Classification Name: Bone Plate
Common/Usual Name: Bone Plating System
Trade Name: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System

ESTABLISHMENT REGISTRATION NUMBER

Inion Ltd. has not yet obtained an Establishment Registration Number.

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 872.4760 bone plates are classified as Class II. Bone Plates have been assigned Product Code 76 JEY.

PREDICATE DEVICES

(1) Bionx Implants Inc.; BioSorbFX (K982139, K982721)
(2) Codman&Shurtleff Inc.; Codman®Craniosorb™ Absorbable Fixation System (K992905)
(3) MacroPore Inc.; Protective Sheet (K972913), MacroPore*MX* Mandibular Fixation System (K000696)
(4) W. Lorenz Surgical; LactoSorb®Trauma Plating System (K955729, K960988, K971870)

INTENDED USE

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation).
a) Fractures of the cranium, midface, maxilla and mandible.
b) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations.
c) LeFort (I, II, III) osteotomies.
d) Pediatric reconstructive procedures.
e) Orthognathic or reconstructive procedures of the cranium, midface, maxilla or mandible.
f) Craniotomy flap fixation.

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is not intended for use in and is contraindicated for: Mandibular tumor resection; Active or potential infection; Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse). The system is not intended for use in the mandible without appropriate maxillomandibular fixation.

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System consists of fixation plates, meshes and screws. Plates are provided in the various shapes and sizes typical of other marketed fixation devices. The system will be provided sterile to the user and is not to be resterilized.

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System implants are designed to be used with a customized instrumentation consisting of drill bits, bone taps, screw driver blade, screw driver handle, screw applicator, plate benders and a heating device. Instruments are made of surgical grade stainless steel.

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is made of resorbable polylactic acid/trimethylenecarbonate copolymer. This copolymer degrades *in vivo* by hydrolysis into L-lactic, D-lactic and TMC monomers which are then metabolised by the body. The absorbable Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System implants lose their strength over 18-36 weeks *in vivo* with complete strength loss and resorption within two to four years.

Used properly, in the presence of adequate immobilization, the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System implants maintain accurate alignment of bone fractures and osteotomies after open reduction.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System has the same intended use and principles of operation and very similar technological characteristics as biodegradable plates and fasteners, which have received 510(k) clearance, including the W. Lorenz Surgical; Lactosorb® Trauma Plating System (K955729, K960988, K971870), Bionx Implants Inc.; BioSorbFX (K982139, 982721), Codman&Shurtleff Inc.; Codman®Craniosorb™ Absorbable Fixation System, MacroPore Inc.; Protective Sheet (K972913) and MacroPore*MX* Mandibular Fixation System (000696).

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System retains sufficient strength to fulfil its intended function during the healing period of the fracture or osteotomy, and device material and degradation by-products are biocompatible, with no short- or long-term safety concerns. Furthermore, there are no new risks associated with use of the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System as compared to the predicate biodegradable implants listed above.

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System performance data demonstrate that the strength and degradation profile reduces the risks of fragment dislocation and foreign-body reaction. Therefore, the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is substantially equivalent to above mentioned predicate Class II devices used for fixation of small bony fragments in low load-bearing fractures and osteotomies. Differences between the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System and these predicate devices do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2001

Ms. Hanna Marttila
Regulatory Affairs Coordinator
Inion, Limited
3 Sorinkatu
FIN-33100 Tampere
FINLAND

Re: K010352
Trade Name: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: January 31, 2001
Received: February 6, 2001

Dear Ms. Marttila:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number:
Device Name: Inion CPS ™ 1.5/2.0/2.5 Bioabsorbable Fixation System

Indications For Use:

Indications:

A. General indications: The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation).
B. Specific indications:
    - Fractures of the cranium, midface, maxilla and mandible.
    - Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations).
    - LeFort (I, II, III) osteotomies.
    - Pediatric reconstructive procedures.
    - Orthognathic or reconstructive procedures of the cranium, midface, maxilla or mandible.
    - Craniotomy flap fixation.

Contraindications:

The Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System is not intended for use in and is contraindicated for:

1. Mandibular tumor resection
2. Active or potential infection
3. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse)
4. DO NOT USE in the mandible without appropriate maxillamandibular fixation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K010352